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Indian Standard

SPECIFICATION FOR MICROWAVE DIATHERMY EQUIPMENT FOR THERAPEUTIC PURPOSES

UDC 615·832·42 : 615·841

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NEW DELHI 110002

Gr 3 *April* 1989

AMENDMENT NO. 1 JANUARY 1992
TO
IS 12311 : 1987 SPECIFICATION FOR MICROWAVE DIATHERMY EQUIPMENT FOR THERAPEUTIC PURPOSES

(*Page* 2, *clause* **6.2.2**) — Insert the following new caluse after **6.2.2** :

'**6.2.3** *Standard Marking* — The equipment may also be marked with the Standard Mark. The details are available with the Bureau of Indian Standards.'

(MHD 19)

Reprography Unit, BIS, New Delhi, India

Indian Standard

SPECIFICATION FOR MICROWAVE DIATHERMY EQUIPMENT FOR THERAPEUTIC PURPOSES

0. FOREWORD

0.1 This Indian Standard was adopted by the Bureau of Indian Standards on 18 December 1987, after the draft finalized by the Electromedical Equipment Sectional Committee had been approved by the Electrotechnical Division Council.

0.2 Diathermy equipment is employed to produce heating in the tissues of the body for therapeutic or surgical purposes. Diathermy equipment operating at a frequency not exceeding 300 MHz can be used either for surgical purpose or for therapeutic use. Microwave diathermy equipment, however, operates at a frequency range of more than 300 MHz but not exceeding 30 GHz and is generally used for therapeutic purposes only.

0.3 While preparing this standard, assistance has been derived from IEC 601-2-6 (1984) 'Medical electrical equipment : Part 2 Particular requirements for the safety of microwave therapy equipment', issued by the International Electrotechnical Commission (IEC).

0.4 For the purpose of deciding whether a particular requirement of this standard is complied with, the final value, observed or calculated, expressing the result of a test or analysis, shall be rounded off in accordance with IS : 2-1960*. The number of significant places retained in the rounded off value should be the same as that of the specified value in this standard.

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*Rules for rounding off numerical values (*revised*).

1. SCOPE

1.1 This standard specifies requirements for microwave diathermy equipment of therapeutic purposes used in medical practice (hereinafter referred to as equipment) operating at a frequency range of more than 300 MHz but not exceeding 30 GHz.

1.2 This standard does not apply to the equipment specified for hyperthermia.

2. TERMINOLOGY

2.0 For the purpose of this standard, the following definitions in addition to those given in IS : 1885 (Part 43)-1977* and IS : 8607 (Part 1)-1977† shall apply.

2.1 Applied Part— The entirety of all parts of the equipment including the patient leads which come intentionally into contact with patient to be examined or treated. For some equipment, particular standards may consider parts in contact with the user as an applied part.

For some equipment, an isolated (floating) applied part extends as seen from the patient into the equipment to the point(s) where the prescribed insulation and/or protective impedance is completed.

In this case, the accessible parts of the applicators and their associated connecting cables or waveguides and their connectors, shall also be considered as applied parts.

2.2 Microwave Therapy Equipment — Equipment for treatment of the patient by means of a propagated electromagnetic field in the frequency range of more than 300 MHz but not exceeding 30 GHz.

2.3 Applicator — Radiator, that is, an aerial with a directional effect, such as dipole with reflector, a dipole array, open waveguide or dielectric radiator for local application of microwave energy to the patient.

2.4 Phantom — Device intended to simulate parts of the patient for test purposes.

2.5 Rated Output Power — Value of the maximum high frequency power averaged over at least 1 s which can be fed into a matched load.

2.6 Unwanted Radiation — Microwave radiation which is not incident on the patient for treatment purposes.

2.7 Matched Load — Resistive load normally in the range 50 to 75 Ω which, when replacing the applicator, results in a voltage standing wave ratio (VSWR) not exceeding 1·5 in the applicator connecting cable or waveguide.

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*Electrotechnical vocabulary: Part 43 Electrical equipment used in medical practice.

†General and safety requirements for electrical equipment used in medical practice: Part 1 General.

3. GENERAL REQUIREMENTS

3.1 The provisions of **4** of IS : 8607 (Part 1)-1977* shall apply.

4. GENERAL REQUIREMENTS FOR TESTS

4.1 The provisions of **5** of IS : 8607 (Part 1)-1977* apply except that the additional routine tests given in Appendix A are to be performed.

5. CLASSIFICATION

5.1 The provisions of **6** of IS : 8607 (Part 1)-1977* apply except as follows:

a) Equipment shall be either Class I or Class II, and

b) According to the mode of operation: Continuous operation.

6. MARKING, IDENTIFICATION AND INFORMATION

6.1 The provisions of **7** of IS : 8067 (Part 1)-1977* apply except for the provisions given in **6.2** to **6.5** of this standard.

6.2 Marking on the Outside of the Equipment

6.2.1 *Output* [*see* **7.13** of IS : 8607 (Part 1)-1977*] — The following information shall be marked:

a) Rated output power in watts,

b) Matched load in ohms, and

c) Operating frequency in megahertz or gigahertz.

6.2.2 *Physiological Effects (Symbols and Warning Statements)* — The provisions of **7.15** of IS : 8607 (Part 1)-1977* shall apply except that the symbol for non-ionizing radiation shall be applied to any access cover, the removal of which results in the emission of a microwave power density in excess of 10 mW/cm² when measured under the conditions of **11.4.2**.

Compliance shall be checked by inspection of any access cover for the presence of this symbol. Where an access cover is not so marked, the test of **11.4.2** shall be performed with the access cover removed.

6.3 Additional Marking on the Inside of Equipment or Equipment Parts

6.3.1 The symbol specified in **6.2.2** shall be applied to any internal access cover, the removal of which may result in the equipment failing to comply with the requirements of **11.4.2**.

Compliance shall be checked by the test of **11.4.2** with the internal access cover removed if it is not marked with the above symbol and also with any external access cover not bearing this symbol, removed.

6.3.2 Symbol for consult accompanying documents shall be displayed on or near components or on panels giving access to components, the adjustment or replacement of which may result in the equipment failing to comply with the requirements for interference suppression.

Compliance shall be checked by inspection.

6.4 Instruction for Use

6.4.1 The instructions for use shall contain the following statements and information:

a) The correct procedures for positioning the applicator for a particular treatment while minimizing the irradiation of other parts of the body;

b) Advice that the output power should be switched off when the applicator is being positioned for treatment;

c) Advice that the applicator should not be directed towards the eyes for tests;

d) A recommendation that the patient should be provided with microwave protection goggles, where appropriate;

e) Advice on the potential hazards of conductive objects or materials near the patient:

Microwave energy should not be applied to persons wearing metallic jewellery or clothing containing metallic material (for example, metallic buttons, clips or thread). Parts of the body of the patient containing metallic implants (for example, a medullary nail) should not be treated unless specialized medical advice is obtained. Hearing aids should be removed from the body. Patients with implanted cardiac pacemakers or electrodes should be excluded from treatment with microwaves and from areas where the equipment is operated;

f) Confirmation that when small areas of the body, for example a wrist, are treated, the applicator should be positioned so that the sensitive areas (for example, eyes, tests) are not in the line of the radiation which is not intercepted by the area (wrist) being treated.

g) Information on type and the size of the applicator recommended for treating various parts of the body and the maximum power allowable for particular applicator;

h) A warning statement that persons not receiving treatment should not be allowed to remain within a distance of 1·5 m from a microwave applicator while it is being used for treatment;

j) The user's attention should be directed to the need for care when handling the applicators since rough handling may change the directional characteristics of the applicator; and

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*General and safety requirements for electrical equipment used in medical practice: Part 1 General.

k) The advice that the patients with reduced thermal sensitivity in the proposed area of treatment should normally be not treated with microwave therapy.

6.5 Technical Description — The technical description supplied with the equipment shall provide information on the precautions to be observed when the warning symbols mentioned in **6.2.2** and **6.3** are displayed.

7. POWER INPUT

7.1 The provisions of IS : 8607 (Part 1)-1977* apply with the equipment operated as specified in **15.1.2**.

8. GENERAL SAFETY REQUIREMENTS

8.1 Provisions of IS : 8607 (Part 1)-1977* shall apply.

9. PROTECTION AGAINST ELECTRIC SHOCK HAZARDS

9.1 Provisions of IS : 8607 (Part 2)-1978† shall apply except that the live parts include parts which are energized at the operating frequency.

9.2 Microwave equipment shall not be Class III equipment.

9.3 Enclosures and Protective Covers

9.3.1 Provisions of **6** of IS : 8607 (Part 2)-1978† apply except that for the purposes of this standard, the live parts include parts which are energized at the operating frequency.

9.4 Continuous Leakage Currents and Patient Auxiliary Currents

9.4.1 Provisions of **9** of IS : 8607 (Part 2)-1978† apply except as given in **9.4.1.1**.

9.4.1.1 The patient leakage current from accessible parts of a floating applied part shall not exceed the limits given in Table 1 of IS : 8607 (Part 2)-1978† when tested as specified in **9.4.1.2**.

9.4.1.2 Compliance shall be checked by measurement of the patient leakage current in such a way that no rf oscillations occur, only dc and low frequency voltage being present.

NOTE — As small leakage currents at low frequency cannot be easily measured in the presence of hf currents, the high-frequency generator is disabled during the tests.

9.5 Dielectric Strength — Provisions of **10** of IS : 8607 (Part 2)-1978† shall apply.

10. PROTECTION AGAINST MECHANICAL HAZARDS

10.1 Provisions of IS : 8607 (Part 3)-1970* shall apply.

11. PROTECTION AGAINST HAZARDS FROM UNWANTED OR EXCESSIVE RADIATION

11.1 Provisions of IS : 8607 (Part 4)-1985† shall apply except for the following modifications.

11.2 X-radiation — The ionizing radiation emitted by the equipment utilizing vacuum tubes excited by voltages exceeding 5 kV shall not produce an exposure exceeding 129 nC/kg (0·5 mR) in 1 h at a distance of 5 cm from the equipment.

Compliance shall be checked by measurement of exposure or exposure rate with a radiation detector suitable for the energy of the emitted radiation. In order to average the exposure of narrow beams over the appropriate area, the detector shall have an entry window with an area of approximately 10 cm^2.

The relevant high voltage source(s) in the equipment shall be adjusted to the most unfavourable value possible by internal or external adjustments means provided for such purpose. Single failures of components causing the most unfavourable situation shall be provoked.

11.3 Alpha, Beta, Gamma, Neutron Radiation and Other Particle Radiation — These radiations are absent in microwave therapy equipment.

11.4 Microwave Radiation

11.4.1 Unwanted radiation shall not exceed 10 mW/cm^2 at a distance of 1 m from the front of the applicator and 25 cm from the rear of the applicator when tested as described below (*see* Fig. 1).

Compliance shall be checked by the following test:

The equipment is first operated on the matched load with the output adjusted to 100 W or the maximum output power specified for each applicator, whichever is the least. Using this power level, the matched load is replaced by each applicator in turn.

The power density of the unwanted radiation is measured with each applicator placed at the maximum distance recommended by the manufacturer for the relevant applicator from a phantom consisting of a cylinderical container, 20 cm

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*General and safety requirements for electrical equipment used in medical practice: Part 1 General.

†General and safety requirements for electrical equipment used in medical practice: Part 2 Protection against electric shock.

*General and safety requirements for electrical equipment used in medical practice: Part 3 Protection against mechanical hazards.

†General and safety requirements for electrical equipment used in medical practice: Part 4 Protection against unwanted or excessive radiation.

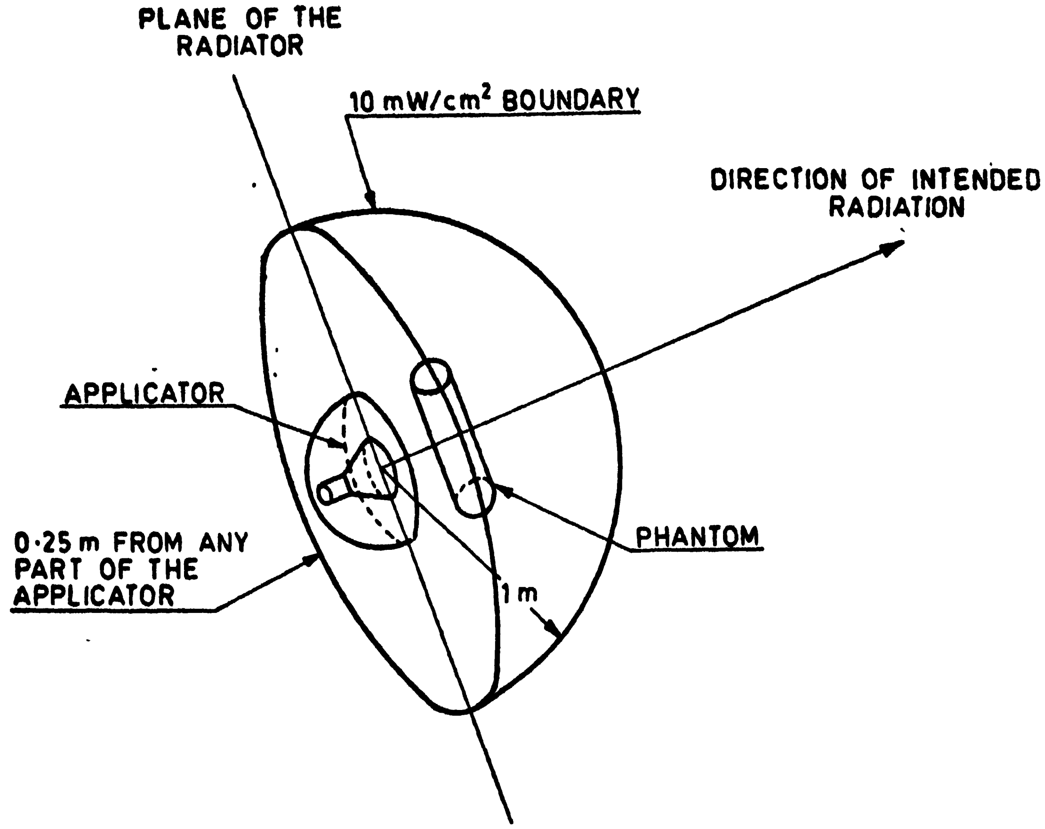
PLANE OF THE RADIATOR
10 mW/cm² BOUNDARY
DIRECTION OF INTENDED RADIATION
APPLICATOR
PHANTOM
0·25 m FROM ANY PART OF THE APPLICATOR
1 m

FIG. 1 MEASUREMENT OF UNWANTED RADIATION

diameter × 50 cm long, made of low-loss material, for example acrylic, filled with a solution of 9 g sodium chloride per litre of water.

NOTE — This requirement limits unwanted radiation and a 'safety zone' around the applicator is defined. The test is performed using a power not exceeding 100 W, as most treatments are made using powers not exceeding 100 W.

In normal use, the user is not continuously exposed to microwave radiation but is in close proximity to the equipment for short periods only. Moreover, the instructions for use warn the user not to be within 1·5 m of an applicator during the treatment.

During positioning of the patient and the applicator, the output is switched off.

Under these conditions, the requirements specified provide for an adequate margin of safety.

11.4.2 The leakage of microwave radiation from the equipment enclosure shall not exceed 10 mW/cm² when measured as described below.

Compliance shall be checked by the following test:

The equipment is connected to a screened matched load and operated at the rated output power. The microwave power density at any point 5 cm from the external surface is measured.

NOTE — The distance at which the measurement is performed provides for an adequate margin of safety taking into account the way the equipment is used.

11.4.3 For requirements of limitation of the microwave power intentionally delivered to the patient (*see* **15.2.1**).

12. PROTECTION AGAINST HAZARDS OF EXPLOSIONS IN MEDICALLY USED ROOM

12.1 Provisions of IS : 8607 (Part 5)-1983* shall apply.

13. PROTECTION AGAINST EXCESSIVE TEMPERATURES, FIRE AND OTHER HAZARDS

13.1 Provisions of IS : 8607 (Part 6)-1984* shall apply.

13.2 Excessive Temperatures — Microwave equipment shall be tested following the conditions specified for equipment for continuous operation in **3.4** of IS : 8607 (Part 6)-1984† and in accordance with the test of **15.1.2** of this standard.

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*General and safety requirements for electrical equipment used in medical practice: Part 5 Protection against explosion hazards.

†General and safety requirements for electrical equipment used in medical practice: Part 6 Protection against excessive temperature fire and other hazards.

14. CONSTRUCTION

14.1 Provisions of IS : 8607 (Part 7)-1985* shall apply.

14.2 Enclosures and Covers — Any access cover or enclosure, the removal of which may result in the equipment failing to comply with the requirement of **11.4.2** (shielding against unwanted radiation) shall be removable only with the aid of a tool.

Compliance shall be checked by inspection.

14.3 Control of Output Power — Therapeutic microwave equipment shall incorporate provision, other than by means of detuning the microwave circuit associated with the radiating head, for adequately controlling the output power.

14.4 Dosage Level Indicator — Therapeutic microwave equipment shall be provided with a means of indicating the level of output power. The means shall be no less effective than a meter calibrated directly in watts output.

14.5 Control by Patient — Therapeutic microwave equipment shall be provided with readily accessible means to enable the patient to discontinue the treatment at will.

15. PERFORMANCE REQUIREMENTS

15.1 Accuracy of Operating Data — Provisions of 3 of IS : 8607 (Part 8)-1985† shall apply except as given in **15.1.1** and **15.1.2**.

15.1.1 Any incorporated indication of the output power may be in absolute units or in relative units.

For an absolute indication, the measured output power shall not deviate from the indicated value by more than ±30 percent of the maximum output power of the selected range.

A relative indication shall not display numerical values which may be confused with the actual output power.

Compliance shall be checked by inspection and the output power test according to **15.1.2**.

NOTE—Since the rf output power used depends largely on the subjective reaction of the patient, the requirements specified are considered to provide for an adequate degree of safety.

15.1.2 When measured immediately after any warming-up period specified in the instructions for use, the maximum output power shall not differ from the rated output power by more than ±30 percent.

Compliance shall be checked by measurement of the output power.

The applicator is replaced by the matched load and the maximum output power into this load is measured with an error not exceeding ±10 percent.

NOTE — The specified accuracy of ±30 percent is considered to be adequate from the standpoint of safety and takes into account the errors inherent in microwave power measurements.

15.2 Protection Against Incorrect Output — Provision of **4** of IS : 8607 (Part 8)-1985* shall apply except as given in **15.2.1** to **15.2.5**.

15.2.1 The rated output power of microwave therapy equipment shall not exceed 250 W.

Compliance shall be checked by comparison of the rated output power with the specified limit.

15.2.2 The microwave power to an applicator intended for direct contact with the body of the patient and having a contact area of 20 cm^2 or less shall not exceed 25 W.

Compliance shall be checked by measurement of the contact area and of the power according to **15.1.2**.

15.2.3 Equipment shall incorporate a means (an output control) to enable the power output to be reduced to 20 percent or less of the maximum output power of each range or to 20 W, whichever is the least.

Compliance shall be checked by the measurement of the output power according to **15.1.2**.

15.2.4 Equipment shall be so designed that the output cannot be energized unless the output control is first set to the minimum position so that the patient may not be treated inadvertently at an excessive power level.

The requirement shall also be met after the interruption and the restoration of the mains supply.

Compliance shall be checked by inspection and functional test.

15.2.5 Equipment shall be provided with an adjustable timer which de-energizes the output after a preselected operating period. The timer shall have a range not exceeding 30 min and an accuracy of ±1 min.

Compliance shall be checked by inspection, functional test and measurement of the operating time.

NOTE — Microwave therapy is often performed without continuous supervision. Therefore, a timer for switching off is essential.

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*General and safety requirements for electrical equipment used in medical practice: Part 7 Construction.

†General and safety requirements for electrical equipment used in medical practice: Part 8 Behaviour and reliability.

*General and safety requirements for electrical equipment used in medical practice: Part 8 Behaviour and reliability.

APPENDIX A

(*Clause* 4.1)

TESTING DURING MANUFACTURE AND/OR INSTALLATION

A-1. ADDITIONAL ROUTINE TESTS

A-1.1 Measurement of operating frequency with the equipment coupled to the matched load.

A-1.2 Verification of the rated output power as specified in **15.1.2**.

A-1.3 Measurement of the patient leakage current under the conditions specified in **9.4** of this standard.

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Printed at Swatantra Bharat Press, Delhi (India)